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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,290	03/24/2004	Cindra A. Widrig Opalsky	215105.00608	3910

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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04/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/807,290	Applicant(s) OPALSKY ET AL.	
	Examiner Lyle A. Alexander	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-96, 98-126, 128-167 and 173-215 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-96, 98-126, 128-167, 173-215 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The 2/3/09 and the 2/5/09 remarks and amendments have overcome the 9/23/08 non-final rejections. However, upon updating the search a new pertinent reference was found and has been applied below in the following new grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 90-96, 98-126, 128-167, 173-174, 182 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 90 is not clear how the sample is meter in the overflow chamber. Is the pump used to pump the sample from the holding chamber into and through the overflow chamber? Similarly, the claim is not clear how the metered sample is mixed with the reagent. How is the reagent moved into the analysis location? Finally, the claim is not clear what steps are performed by the claimed "closable sample entry port."

Claim 98 is not clear how the sample is forced into the overflow chamber by closure of the sample entry port. Presumably, closure of the port must cause a change in pressure or some other force must be exerted to force the sample. It is not clear how simply closing a port can exert a force on a fluid. For the purposes of examination, it will be assumed the pump changes the pressure in the system to force the sample into the overflow chamber.

Claim 101 is not clear what method steps are performed by the “pre-sensor chamber.”

Claim 115 is not clear how the overflow chamber is treated to impart a high energy surface to the interior. For the purposes of examination, it will be assumed pressure is intended.

Claim 120 is not clear what method steps are intended by “... a lower interior surface-to-volume ration ...” because these appear to be structural limitations. Furthermore, even if these limitations were considered as a structural limitations, it is not clear what structure is intended by “... a lower...”.

Claim 125 is not clear what products are intended. If these are well known in the art, please reference the appropriate portions of the specification or supply corroborating evidence in your response.

Claim 182 is not clear what structure is intended by a “pre-sensor.”

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 90-96, 98-126, 128- 136, 144-146, 148, 150-158, 167, 173-203 and 212-215 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sheppard et al. (USP 6,143,247).

Sheppard et al. a method and apparatus for the detection of an analyte in a sample. Column 3 lines 18-25 teach a detection chamber where a specific binding reagent is supplied that binds to the analyte of interest. This chamber has been read on the claimed "analysis location." Column 3 lines 65-67 teaches various detector that have been read on the claimed "sensor." Column 4 lines 23-30 teach the structure also includes "... input means, fluid waste receptacles, overflow reservoirs, wash buffer reservoirs, fluid waste receptacles or reservoirs containing ..." that have been read on the claimed "holding chamber" and "overflow chamber." Column 6 lines 1-12 teach a metered amount of sample is transferred to a detection cell and any excess fluid from the metered amount is placed into an overflow chamber. The metered amount is between 10 microliter and 150 microliters. This has been read on the claimed "metering a portion of the sample by retaining the excess in the overflow chamber" and the claimed volume ranges. Column 13 lines 34-45 teach the sample can be moved by mechanical means such as pumping of air which has been read on the claimed "pump." The claimed "capillary stops" have been read on the taught pump that controls the flow of the fluids through the device (e.g. stops and starts the flow). Column 16 lines 9-15 teach treating the surface with a gas plasma which has been read on the claimed "corona treated" surface. Column 17 lines 26-36 teach treatment of the surface with hydrophobic materials and has been read on the claimed "hydrophobic areas."

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Sheppard et al. teach dyes and buffers such as HEPES that have been read on the claimed reagents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 137-143,143,149,159-166,204-211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. in view of Zelin et al. (USP 5,124,661).

See Sheppard et al. supra.

Sheppard et al. are silent to the claimed conductimetric and amperometric sensors.

Zelin et al. in their abstract a reusable blood testing cartridge that comprises a combination of ampermetric and conductometric sensors for the analysis of blood. Column 4 lines 8-19 teach these sensors are advantageous because they do not need to be replenished with chemicals.

It would have been within the skill of the art to modify Sheppard et al. in view of Zelin et al. and use a combination of ampermetric and conductometric sensors to gain the above advantages.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1797

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Primary Examiner, Art Unit 1797